

K063405

510[k] Summary of Safety and Effectiveness

JAN - 8 2007

Submitter Information

Company: Radiant Medical, Inc.
250 Chesapeake Drive
Redwood City, CA 94063
(650) 363-8000

Contact Person: Scott A. Wilson, Ph.D.
Vice President of Regulatory Affairs, Quality Assurance &
Intellectual Property

Summary Date: November 2006

Name and Classification

Proprietary Name: The Reprieve® Endovascular Temperature Therapy System

Regulation Name: Thermal regulating system

Regulation No.: 870.5900

Class: II

Product Code: NCX

Predicate Device

- a) Radiant Medical SetPoint® Endovascular Temperature Management System (K012512).

Indication for Use

The Reprieve® Endovascular Temperature Therapy System is indicated for use in cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care.

Description of Device

The Reprieve System consists of a single-use, heparin-coated, central venous catheter; a single-use, heat exchange cassette; an integrated temperature probe; and an external controller. The Controller unit has a user interface to select operating parameters and is connected to the Catheter via the Cassette and extension lines. The catheter is designed for placement in the inferior vena cava via the femoral vein using a 12 Fr hemostatic introducer sheath.

Summary of Technological Characteristics

The Reprieve System uses established technology, materials, and construction techniques. The system employs standard heat conduction technology to warm or cool the blood using circulating warm or cool fluid in a closed loop system. The SetPoint System accomplishes this heat exchange through a catheter, located in the inferior vena cava, via the femoral vein, thereby adding heat to or removing heat from the blood by means of counter current heat exchange. The microprocessor based Controller circulates saline through the catheter and cassette and allows the saline temperature to be raised or lowered as it passes through a heat exchanger in thermal communication with a process fluid unit within the Controller. Patient temperature is constantly measured by the Controller using a temperature probe (K042388) integrated with the catheter.

Performance Test

The Reprieve Endovascular Temperature Therapy System has been tested for system performance. In addition the Catheter has been tested for functionality in accordance to BS EN ISO 10555, for biocompatibility in accordance to ISO 10993, and for sterility in accordance to ISO 11137. The controller has been tested for electrical safety in accordance to IEC 60601.

Conclusion

Based upon the successful completion of performance verification tests and the comparison to the predicate devices, the Radiant Medical Reprieve Endovascular Temperature Therapy System performs with safety and effectiveness equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Radiant Medical
% Scott A. Wilson, Ph.D.
Vice President
Regulatory Affairs and Quality Assurance
250 Chesapeake Drive
Redwood City, California 94063-4745

JAN - 8 2007

Re: K063405

Trade/Device Name: Reprieve® Endovascular Temperature Therapy System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: NCX
Dated: December 1, 2006
Received: December 4, 2006

Dear Dr. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063405

Device Name: Reprieve® Endovascular Temperature Therapy System

Indications For Use: The Radiant Medical Reprieve® Endovascular Temperature Therapy System is indicated for use in cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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